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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., AND NORTON
(WATERFORD) LTD.,

PLAINTIFFS,

V.

CIPLA LTD, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC

DEFENDANTS

Consolidated Civil Action No.
2:20-CV-10172-JXN-MAH

CONFIDENTIAL

SUPPLEMENTAL INVALIDITY EXPERT REPORT OF GREGOR ANDERSON

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I. INTRODUCTION

1. Counsel for Defendants Cipla Ltd. (“Cipla”), Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma, LLC (collectively, “Aurobindo”) (all collectively, “Defendants”) have retained me to provide technical assistance in this action.

2. I understand that Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, “Teva”) allege that Defendants infringe U.S. Patent Nos. 9,463,289 (“the ’289 Patent”); 9,808,587 (“the ’587 Patent”); 10,086,156 (“the ’156 Patent”); and 10,561,808 (“the ’808 Patent”) (collectively, “the Asserted Patents”).¹

3. In this supplemental invalidity expert report, I have been asked to provide opinions regarding whether the asserted claims of the ’156 Patent are anticipated in view of Plaintiffs’ identification of a datum plane line for the first time in Dr. David Lewis’s Opening Expert Reports to Cipla and Aurobindo (“Lewis Opening Report”), assuming Plaintiffs and Dr. Lewis are allowed to make this argument.

4. I am an independent expert and not a regular employee of any party or counsel to any party in this lawsuit.

II. TOPICS OF OPINIONS

5. In this supplemental report, I offer opinions on the following general topics:

- Whether the ’156 Patent is anticipated.

¹ I understand that Plaintiffs have agreed to provide covenant not to sue on U.S. Patent No. 10,695,512, and that the parties have agreed that the patent will be dismissed from the litigation. However, as of signing this report, I understand the patent has not yet been dismissed. Accordingly, I reserve the right to address the validity of the ’512 Patent later, if it is not dropped from the case.

III. QUALIFICATIONS; COMPENSATION; PRIOR TESTIMONY

6. I am the same Gregor Anderson who served an Expert Report on Invalidity on April 29, 2022 (“Anderson Opening Report”).

7. My qualifications, compensation, and priority testimony are set forth in detail in Sections III, IV, and V the Anderson Opening Report, which I incorporate in full herein. In addition, my Curriculum Vitae, which generally sets forth my experience, my qualifications, and my publications for over three decades, is attached to the Anderson Opening Report as Exhibit A

IV. MATERIALS AND INFORMATION CONSIDERED

8. In forming my opinions, I have considered the materials discussed in the Anderson Opening Report, as well as documents and information listed in Exhibit B to that report. I have also considered the Lewis Opening Report and the materials listed in Exhibit B hereto.

9. Additionally, in forming my opinions, I have relied upon my education, training, and experience in the medical device industry, my personal inspection of the Plaintiffs’ Devices, and my evaluation of references available to a POSA at the time the Asserted Patents were filed.

10. The opinions set forth in this report are based on the information of which I am aware to date. I reserve the right to supplement this report should additional information become available, or should Teva present new issues in response to this report.

V. APPLICABLE LEGAL STANDARDS

11. The Anderson Opening Report sets forth the legal standards which I have applied in forming my opinions. *See* Anderson Opening Report at Section VII.

VI. CLAIM CONSTRUCTION

12. The Anderson Opening Report sets forth the claim constructions which I have applied in forming my opinions. *See* Anderson Opening Report at Section VIII.

VII. BACKGROUND OF THE RELEVANT TECHNOLOGY

13. The Anderson Opening Report sets forth the background of the relevant technology, which I incorporate in full herein. *See* Anderson Opening Report at Section X.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

14. The Anderson Opening Report sets forth the level of ordinary skill in the art, which I incorporate in full herein. *See* Anderson Opening Report at Section XI.

IX. SUMMARY OF THE ASSERTED PATENTS

15. The Anderson Opening Report sets forth a summary of the Asserted Patents, which I incorporate in full herein. *See* Anderson Opening Report at Section XII.

X. SUMMARY OF THE ACCUSED PRODUCTS²

16. The Anderson Opening Report sets forth a summary of the Accused Products, which I incorporate in full herein. *See* Anderson Opening Report at Section XIII.

XI. PRIOR ART

17. The Anderson Opening Report sets forth a summary of the Prior Art, which I incorporate in full herein. *See* Anderson Opening Report at Section XIV.

XII. INVALIDITY OF THE '156 PATENT

18. The Anderson Opening Report sets forth a summary of the '156 Patent, which I incorporate in full herein. *See* Anderson Opening Report at ¶¶ 318-325. I understand that Plaintiffs are asserting claims 1, 9, and 11-13 of the '156 Patent.³

² Although I cite to the Cipla ANDA Product throughout this report, I understand the actuators and dose counters of both Defendants' ANDA Products to be materially the same.

³ From my review of Dr. Lewis's Opening Report, I understand that Plaintiffs are no longer asserting claim 2 of the '156 Patent against Defendants. Accordingly, I reserve the right to address the validity of claim 2 over the '552 Publication later, if Plaintiffs are allowed to reassert it.

19. Claim 1 is the only independent claim of the '156 Patent. Claims 9, and 11-13 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

A ratchet wheel having a plurality of circumferentially spaced teeth,
an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,
a dosage indicator associated with the count pawl,
wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

A. Summary of the Relevant Prosecution History

20. I have reviewed the prosecution history of the '156 Patent. The Applicants filed the patent application which lead to the '156 Patent on April 29, 2015 with a single independent claim.

21. On June 17, 2016, the Examiner rejected claims, including the sole independent claim as being anticipated by U.S. Patent No. 6,446,627 ("Bowman"). *See* '156 Patent Prosecution History, June 17, 2016 Office Action at 3.

22. In response to the Examiner's rejection, the Applicants amended claim 1 to recite:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

- a ratchet wheel having a plurality of circumferentially spaced teeth,
- an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

- a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

- a dosage indicator associated with the count pawl,

wherein the canister fire sequence comprises a canister fire configuration and a count configuration wherein:

- in the canister fire configuration the actuator pawl and ratchet wheel are in a first position at which the canister fires medicament, and

- in the count configuration the actuator pawl is in the first position or in a second position which is just after the first position, and in the count configuration the count pawl has just resiliently jumped over the second tooth and the dosage indicator has indicated a count.

See '156 Patent Prosecution History, September 9, 2016 Office Action Response at 2.

23. On October 20, 2016, the Examiner issued a final rejection, again rejecting the claims over Bowman, explaining: "The applicant has amended the claims to further describe (1) a 'canister fire configuration' where the medicament is fired which is before the count pawl jumps over a tooth of the ratchet wheel and (2) a 'count configuration' which is just after the count pawl jumps over a tooth of the ratchet wheel. The examiner maintains that [Bowman] clearly has both of these configurations." '156 Patent Prosecution History, October 20, 2016 Final Office Action at 2.

24. Following the Examiner's final rejection, the Applicants amended the claims to recite:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially spaced teeth,
an actuator comprising an actuator pawl arranged to engage with a first tooth
of the ratchet wheel, wherein the actuator can be driven in response to
canister motion to drive the ratchet wheel to rotate,
a count pawl arranged to engage with a second tooth of the ratchet wheel,
wherein as the ratchet wheel is driven by the actuator to rotate, the count
pawl rides along a forward surface of the second tooth and resiliently jumps
over the second tooth,
a dosage indicator associated with the count pawl,
~~wherein the canister fire sequence comprises a canister fire configuration and
a count configuration wherein:~~
 ~~in the canister fire configuration the actuator pawl and ratchet wheel are
 in a first position at which the canister fires medicament, and
in the count configuration the actuator pawl is in the first position or in a
second position which is just after the first position, and in the count
configuration the count pawl has just resiliently jumped over the second tooth
and the dosage indicator has indicated a count.~~
wherein the actuator is arranged to define a first reset position in which the
actuator pawl is brought into engagement with the first tooth,
wherein the actuator is further arranged such that, during a canister fire
sequence, when the actuator is in a second position, which is after the first
reset position and at a canister fire configuration, the medicament canister
fires medicament before the dose counter reaches a count configuration, and
when the actuator is in a third position after the second position, the count
pawl resiliently jumps over the second tooth and the dose counter reaches
the count configuration, whereby the dosage indicator has indicated a count.

See '156 Patent Prosecution History, February 21, 2017 Response to Final Office Action at 2.

25. Notably, the claim proposed by the Applicants on February 21, 2017, is identical to the final claim that received allowance, except that it does not include the limitation: “wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.”

26. On March 13, 2017, the Examiner issued an advisory action maintaining their rejection of the pending claims over Bowman, even in view of the revised claim language. The Examiner explained that, like the claim, Bowman teaches that counting must occur after firing.
See '156 Patent Prosecution History, March 13, 2017 Advisory Action at 2.

27. On April 20, 2017 the Applicants filed additional argument, along with a request for continued examination. The Applicants argued that Bowman teach the claimed positions/configurations, arguing that the actuator pawl of Bowman does not engage the ratchet wheel until after firing. *See* '156 Patent Prosecution History, April 20, 2017 Response to Final Office Action at 8.

28. On May 5, 2017, the Examiner issued another rejection, stating “[t]he applicant’s arguments have been carefully considered but are not regarded as persuasive.” *See* '156 Patent Prosecution History, May 5, 2017 Office Action at 2. The Examiner further explained that, “positions 1, 2 and 3 occur in Bowman (pawl embodiment of figure 4 and 6a) and they occur in the order recited in the claims.” *Id.* at 4.

29. On August 22, 2017, the Applicants again responded to the Examiner, without modifying the claims, arguing that Bowman did not anticipate the claims as currently written. *See* '156 Patent Prosecution History, August 22, 2017 Office Action at 6-8.

30. On September 13, 2017, the Examiner issued a Final Rejection, stating that, again, “Applicant’s arguments filed 8/22/2017 have been fully considered but they are not persuasive.” *See* '156 Patent Prosecution History, September 13, 2017 Final Office Action at 2. The Examiner reiterated that, “positions 1, 2 and 3 occur in Bowman (pawl embodiment of figure 4 and 6a) and they occur in the order recited in the claims.” *Id.* at 4. The Examiner emphatically (evidenced by the switch to bolded font and repeated use of exclamation points) rejected Applicants’ arguments to the contrary. *Id.* at 4-6.

31. On March 13, 2018, after more than a year of attempting to persuade the Examiner that Bowman did not anticipate claim 1 as written, the Applicants amended Claim 1 to recite:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the

medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

- a ratchet wheel having a plurality of circumferentially spaced teeth,
- an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
- a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

- a dosage indicator associated with the count pawl,

wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,

wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,

wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

See '156 Patent Prosecution History, March 13, 2018 Response to Final Office Action at 2 (bold emphasis added).

32. Applicants argued that “Bowman does not disclose each and every element of claim

1. In particular, Bowman does not disclose wherein, in the canister fire configuration, the actuator pawl is below the datum plane as claimed.” *Id.* at 7.

33. On May 31, 2018, the Examiner allowed the claims, as amended on March 13, 2018, to issue. The Notice of Allowance stated:

The following is an examiner’s statement of reasons for allowance: The prior art fails to teach or fairly suggest, in the context of all other elements of claim, the limitation, “wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.”

The examiner performed a careful comparison of figure 2 of Bowman with instant figure 9, which shows the now claimed “datum plane” and the “shoulder of a valve

stem block configured to receive the medicament canister.” From this it appears that in Bowman, this datum plane is somewhat below contacting portion of the drive means 50. The actuator pawl of Bowman is above the plane which passes through a shoulder of a valve stem block configured to receive the medicament canister as it advances the counter wheel.

See ’156 Patent Prosecution History, May 31, 2018 Notice of Allowance at 3.

B. The ’552 Publication Anticipates Claims 1, 9, and 11-12

34. As discussed in detail below, in my opinion, each asserted claim of the ’156 Patent is anticipated by the ’552 Publication, when the datum plane is drawn as Dr. Lewis proposes.

35. Bowman is the United States patent of PCT Publication No. WO 98/28033. See Bowman at p. 1. The ’552 Publication explains that “the dose counter of the present invention” is based on that set out in [Figures from WO 98/28033] except that the pawl 60 has been modified.” ’552 Publication at 8:7-9. I understand these similarities to mean that the locations of the actuator pawl and the valve stem block shown in both Bowman and the ’552 Publication to be the same. See Bowman at Fig. 2; ’552 Publication at Fig. 2.

36. ***Preamble: “A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising.”*** To the extent the preamble is limiting, the ’552 Publication discloses this limitation. See ’552 Publication at Abstract (“the present invention relates to a metered inhaler dose counter”); 1:15-18 (“Such metered-dose inhalers typically include a medicament-containing vessel”); 1:20-21 (“The medicament-containing vessel may be a pressurized canister containing a mixture of active drug and propellant”); 3:26-30 (“Actuation of the metering-valve assembly is effected by causing downward movement of the aerosol canister 6 relative to the actuator body 2.”).

37. **Limitation 1A:** “a ratchet wheel having a plurality of circumferentially spaced teeth.” The ’552 Publication discloses “a wheel 30 mounted on a spindle (not shown), the wheel 30 having a plurality of ratchet teeth 32 around its periphery.” *See id.* at 8:10-17. This wheel (yellow), with a driver (or actuator pawl) 28 (blue) is shown in Figure 5, below:

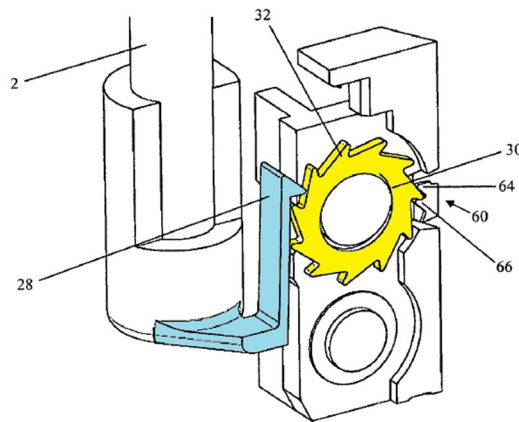


Fig. 5

38. **Limitation 1B:** “an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate.” The ’552 Publication discloses this limitation. In particular, it discloses “an actuator 20” along with “a driver 28 for driving the rotary gear in a step-wise fashion in response to the actuator 20.” *See id.* at 8:10-17. As can be seen in Figure 5, above, driver 29, shown in blue, is an actuator pawl, and it is engaged with a first tooth of a ratchet wheel 30, shown in yellow. The ’552 Publication further explains that, in use, the “user depresses the aerosol canister 6 which causes displacement of actuator 20 . . . In the embodiment shown in Fig. 5, the movement of the rotary gear [(i.e., ratchet wheel 30)] occurs during displacement of the actuator from the first position to the second position.” *Id.* at 9:21-31. As can be seen in Figure 5 below, the actuator (misabeled 2, rather than 20, in the image) is shown in light purple. The

actuator has a boss, shown in green, formed at its base. Driver 28 (actuator pawl shown in blue) is integrally molded with the boss. *See id.* at 4:5-6, 4:12-13, and 8:7:8.

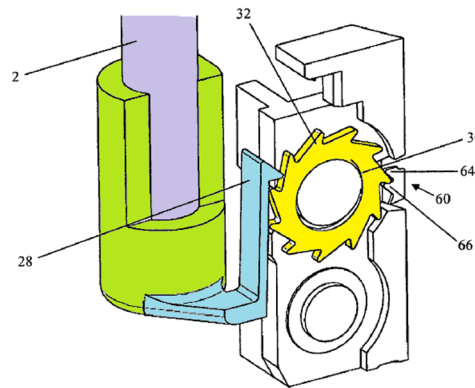


Fig. 5

39. **Limitation 1C:** *“a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth.”*

The '552 Publication discloses a count pawl 60. As can be seen in Figure 5, shown in red, the count pawl engages with a second tooth of the ratchet wheel.

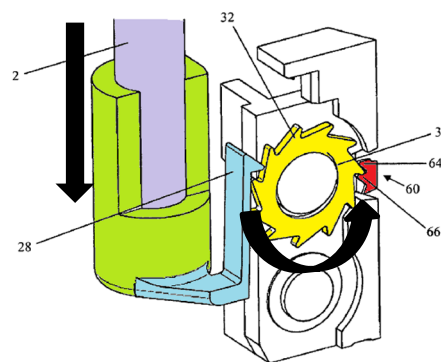
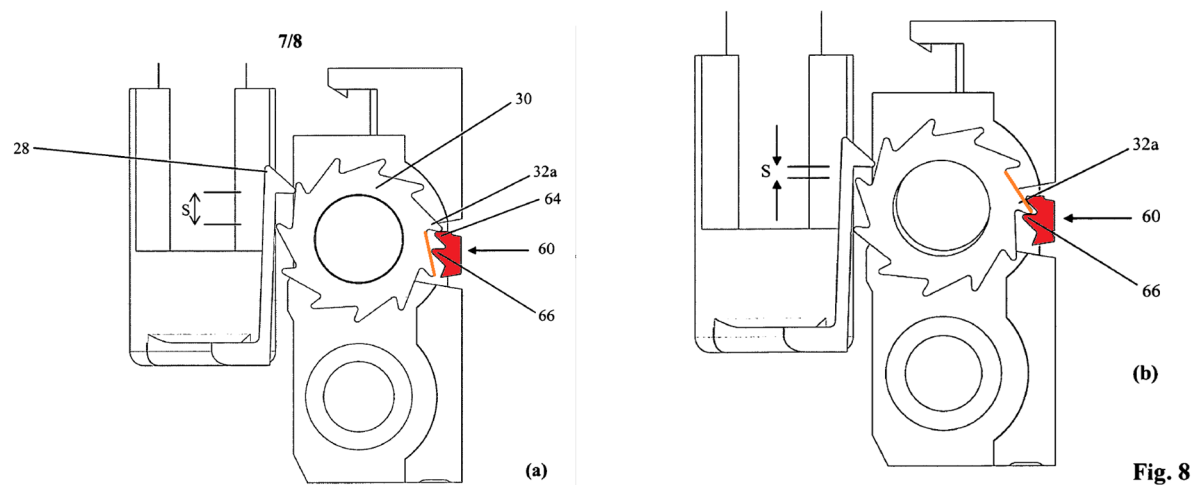


Fig. 5

40. As shown with arrows in the above figure, when the canister is depressed during use, the actuator (purple) is pressed downwards, this movement causes the actuator pawl (blue) to move downwards. As the actuator pawl (blue) is moved the hook, engaged with a first tooth of

the ratchet wheel (yellow), moves downward and rotates the wheel in a counterclockwise direction. As the wheel moves, the count pawl 60 “radially outwardly deforms to allow the wheel 30 to rotate by one tooth 32. The at least two teeth 64, 66 of pawl 60 may be inherently resilient to allow the required radially outward deformation and return.” *Id.* at 10:10-12. In other words, as the wheel rotates, the count pawl rides along the forward surface of the second tooth, and resiliently jumps over the second tooth. *See id.* at 12:11-19. This is also shown in Figures 8a and 8b, which depict the count pawl 30 before and after it has ridden along the front surface of the second tooth (orange) and resiliently jumped over that tooth:



41. **Limitation 1D:** “a dosage indicator associated with the count pawl.” The ’552 Publication also discloses this limitation, explaining that “[t]he [count] pawl 60 radially outwardly deforms to allow the wheel 30 to rotate by one tooth 32.” *Id.* at 10:10. The ’552 Publication further explains that the dose counter of the invention includes a “display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step-wise rotary motion of the rotary gear [(i.e., ratchet wheel)].” *Id.* at 8:15-17.

42. **Limitation 1E:** “wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth.” In use, the dose

counter disclosed in the '552 Publication passes through a first reset position. As can be seen in Figure 8a, above, in the rest position the actuator pawl is not yet engaged with a first tooth. As shown in Figure 8b, once the plunger is compressed the actuator pawl is in connection with the first tooth in order to rotate the ratchet wheel. *See also id.* at 8:10-17, 9:21-31. In order to perform its intended function, it must pass through a position in which the actuator pawl is brought into engagement with the first tooth.

43. I understand that the Parties have proposed different constructions for “first reset position.” I understand that the primary difference in these constructions is that Defendants’ construction indicates that, in the first reset position, the actuator pawl is above the datum plane line,” while Plaintiffs’ construction is silent as to this locational requirement. Although I disagree with where Dr. Lewis has drawn the datum plane line, in my opinion, when the datum plane is drawn as Dr. Lewis proposes, the '552 Publication discloses this limitation under Plaintiffs’ proposed construction.

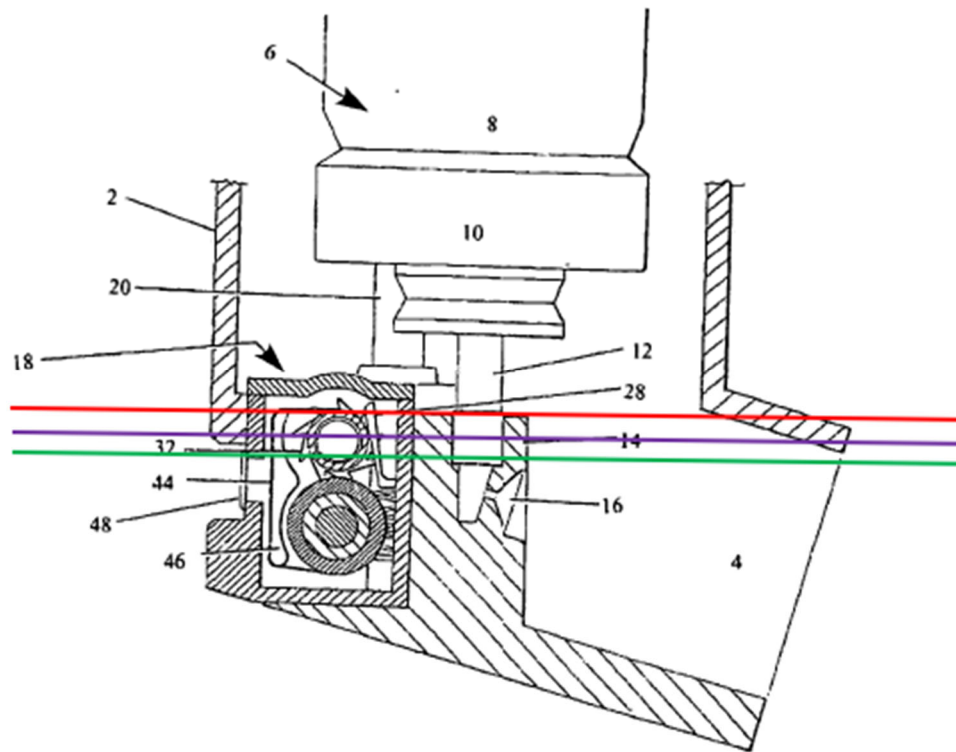
44. ***Limitation 1F: “wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.”***

As discussed above, the downward movement of the canister moves the actuator pawl downwards to rotate the ratchet wheel clockwise until the count pawl jumps over the second tooth, at which point a count is indicated. *See* Paragraphs 38-39 and 43. This full stroke has occurred just after the canister fires (e.g., is in the canister fire configuration). *See* '552 Publication at 10:26-11:4

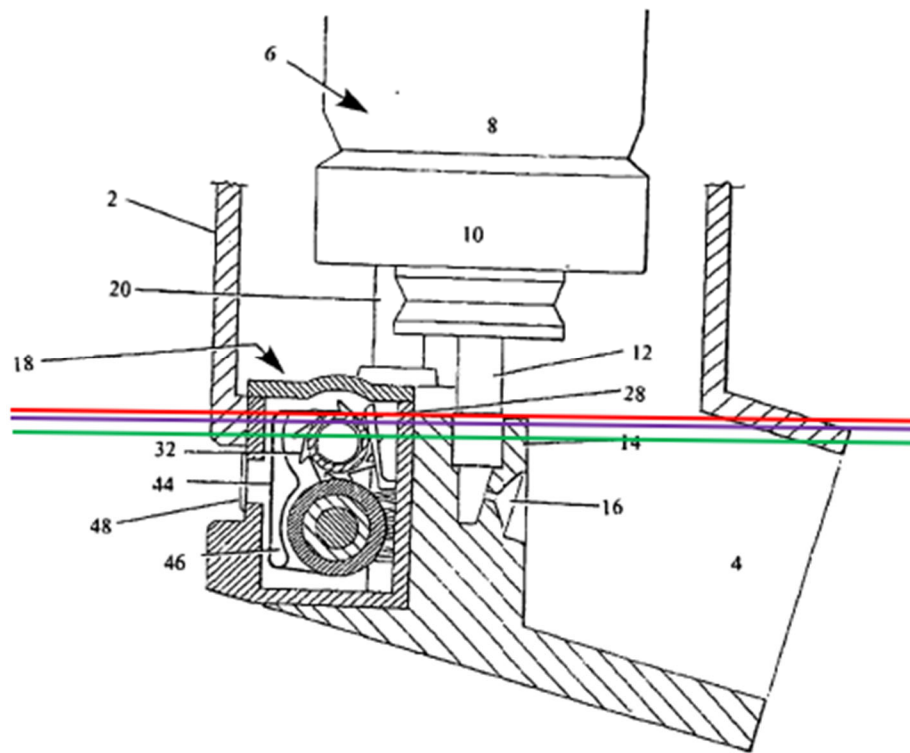
(“The counter mechanism of the type described with reference to WO 98/28033 and in accordance with the present invention must rotate the wheel 30 of the rotary gear by exactly one tooth spacing each time the actuator is depressed. By tooth spacing is meant one tooth pitch, i.e., the radial distance between the same notational point two adjacent teeth 32 on the ratchet-toothed wheel 30. The stroke available for indexing the rotary gear is equal to the full stroke of the actuator 2. Where the metered-dose inhaler is a pressurized inhaler, the stroke available for counting is equal to the full stroke of the medicament canister 6.”)

45. I understand that the Parties have proposed different constructions for “canister fire configuration.” I understand that the primary difference in these constructions is that Defendants’ construction indicates that, in the canister fire configuration, the actuator pawl is below the datum plane line,” while Plaintiffs’ construction is silent as to this locational requirement. In my opinion, the ’552 Publication discloses that the actuator pawl is below the datum plane line when in the canister fire configuration, when Dr. Lewis’s interpretation of a datum plane line is applied.

46. As discussed above, the ’552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed. *See id.* at 8:7-8. The prior art embodiments which the ’552 Publication improved upon disclose that, in the start or rest position, the actuator pawl is below the datum plane as identified by Dr. Lewis (shown with a red line). Based on the rotation distance, when the actuator pawl is brought into engagement with the first tooth (shown with a purple line), but has not yet begun rotating it (e.g., in the first reset position), it is still above the datum plane line. The ’552 Publication discloses that a full stroke, moves the ratchet wheel one full tooth pitch, which would bring the first tooth from the purple line to the green line, at which point the actuator pawl is approximately at or slightly above datum plane line:



47. Even if the first tooth, is considered to be the tooth with the highest possible point on the ratchet wheel, the actuator pawl would still be below the datum plane line in both the first reset position and the fire configuration:



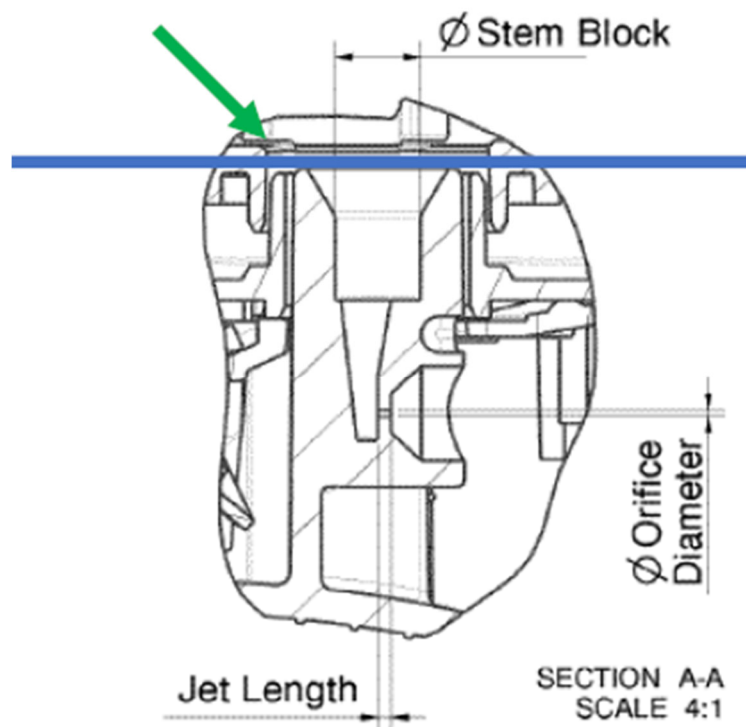
48. I also understand that the Parties have proposed different constructions of “canister fire sequence.” I understand that the primary difference between these constructions is that Defendants’ proposed construction requires that, in the rest or start configuration, the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel. As shown in Figure 8a above, in the start position, the ’552 Publication discloses that the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel.

49. Accordingly, because this limitation is disclosed under both parties’ constructions of disputed terms, my opinion remains the same irrespective of which construction is applied.

50. **Limitation 1G:** “*wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.*” I understand that the Parties have proposed different

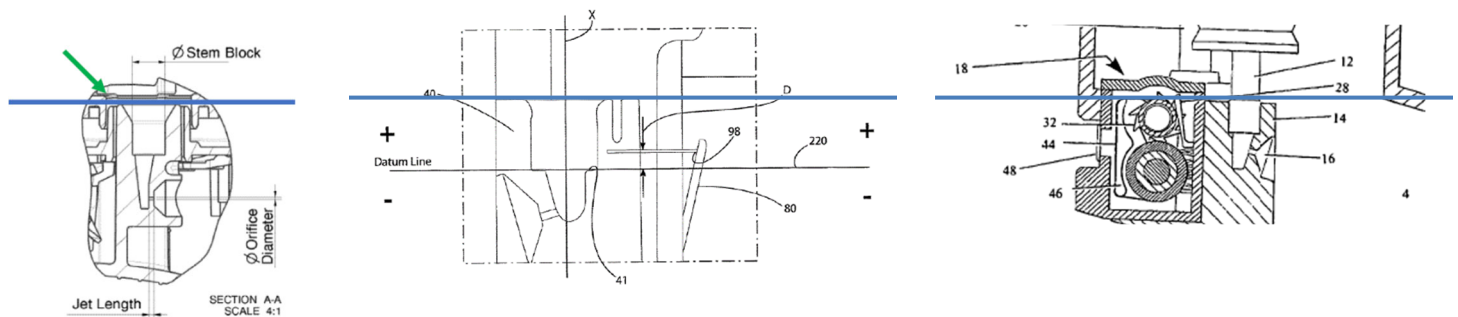
constructions for the phase “datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.” Dr. Lewis has contended that under Plaintiffs’ construction of this phrase, the datum plane line can be drawn at the top of the valve stem block. For all the reasons that I will detail in my forthcoming report responding to Dr. Lewis’s Opening Report, including at least that a POSA would understand from the Prosecution History of the ’156 Patent that the datum plane could not encompass the plane drawn as Dr. Lewis proposes and still allow the patentees to rely on it to overcome the Examiner’s rejection over Bowman as occurred during prosecution, I disagree that a POSA would draw the line where Dr. Lewis has, under either party’s construction. However, for purposes of this supplemental invalidity report only, I have adopted Dr. Lewis’s (incorrect) identification of a datum plane line at the top of the stem block.

51. In the Lewis Opening Report, Dr. Lewis identified the datum plane line at the very top (e.g., the head) of the stem block, as follows:



See Lewis Opening Report to Cipla at ¶ 316.

52. Accepting, for this (incorrect) argument in this supplemental report only, Dr. Lewis's identification of this datum plane as correct, I have applied the same line to both Figure 9 of the '156 Patent, and Figure 2 of the '552 Publication. A comparison of a schematic of Defendants' device, Figure 9 of the '156 Patent, and Figure 2 of the '552 Publication with Dr. Lewis's datum plane drawn in blue is shown below:



See Lewis Opening Report to Cipla at ¶ 316; '156 Patent, Figure 9; '552 Publication, Figure 2.

53. As can be seen in the images above and in paragraphs 45 and 46 (showing datum plane as drawn by Dr. Lewis in red), applying Dr. Lewis's positioning of the datum plane results in the actuator pawl of the '552 Patent being below the datum plane. In addition, this is true irrespective of which position is shown in Figure 2 of the '552 Publication. To the extent Teva contends that it is in the "fire configuration" the actuator pawl is shown to be below the datum plane line. To the extent Teva contends that it is in the rest or first reset position, the downward movement of the canister will push the actuator pawl further below the datum plane. For purposes of my opinion throughout this report, and in my Opening Report, I have determined that Figure 2 depicts the rest position due to the positioning of the canister and the extension of the actuator pin (20).

54. For all of these reasons, under Dr. Lewis's identification of the datum plane, claim 1 of the '156 Patent would have been anticipated by the '552 Publication.

55. Thus, a person of skill in the art would be motivated by the teachings in the '552 Publication, and patient experience, to maintain a shorter distance for the actuator device to move in order to register a dose count, and it would require no more than routine optimization to arrive at a distance of less than 1mm, particularly as the '552 Publication already taught improvements in accuracy where the travel distance between teeth of the count pawl is less than 1mm. Thus, claim 2 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

56. Claims 9 and 11-12 of the '156 Patent, which depend directly or indirectly from claim 1 would have been anticipated for the same reasons set forth with respect to claim 1, above as well as the reasons set forth in detail below.

57. Claim 9 of the '156 Patent depends from claim 1 and recites "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." The '552 Publication discloses that the count pawl and ratchet wheel are arranged such that "[p]referably, the pawl 60 prevents rotation of the rotary gear." *See* '552 Publication at 14:20-21. Accordingly, this limitation is disclosed by the '552 Publication. Thus, claim 9 of the '156 Patent would have been anticipated by the '552 Publication.

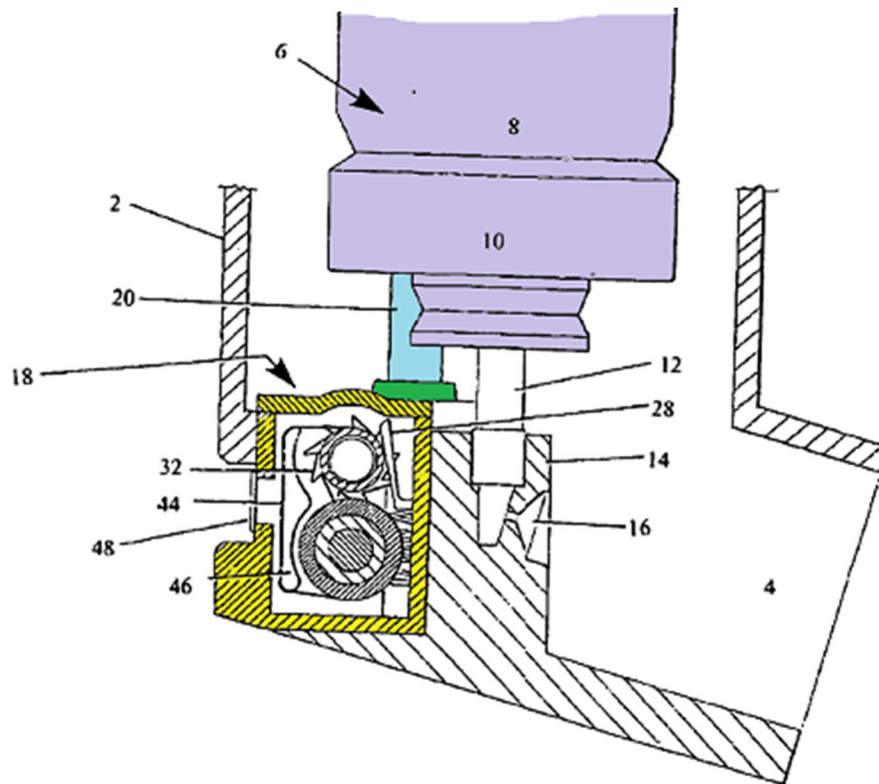
58. Claim 11 depends from claim 1 of the '156 Patent and recites, "[a]n inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter." The '552 Publication discloses this limitation. For example, it discloses the use of a medicament canister in the body, along with a dose counter. *See* 13:14-22, Fig. 9.

Thus, claim 11 of the '156 Patent would have been anticipated by the '552 Publication and the knowledge of the POSA.

59. Claim 12 depends from Claim 11 of the '156 Patent and recites, “[a]n inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.”

60. For the reasons discussed in detail in Section XVI.D of the Anderson Opening Report, this claim is structurally impossible and indefinite.

61. I understand that Plaintiffs have proposed a construction that rewrites the claim, whereby “the body,” when used the second time only, refers to “the dose counter body.” If the claim is not found to be indefinite, and Plaintiffs’ construction is adopted, the '552 Publication discloses this limitation. As discussed above, the '552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed. *See id.* at 8:7-8. Figure 3 discloses the prior art on which the '552 Publication improves. Figure 3 discloses a separate counter chamber (yellow). The entirety of the dose counter 18, including “the body of the dose counter, the ratchet wheel, and the actuator are located inside the separate counter chamber. The actuation member 20 (blue) extends through an aperture (green), such that motion from the canister (light purple) can be translated to the dose counter.



62. Accordingly, to the extent this claim is not indefinite, and Plaintiffs’ construction is adopted, the ’552 Publication anticipates claim 12.

63. I understand the Parties have proposed different constructions for “separate counter chamber.” I understand the primary difference between the two constructions is that Defendants’ proposed construction requires the chamber be formed by the inner walls of the body of the inhaler, while Plaintiffs’ proposed construction merely requires a separate chamber. This limitation is met under Plaintiffs’ construction by the counter chamber shown in yellow in Figure 3, above. In addition, as shown in Figure 3, this chamber is formed by the inner walls of the inhaler body, thus, to the extent this claim is found definite, my opinion does not change if Defendant’s construction of “separate counter chamber” is adopted.

XIII. REVISION OR SUPPLEMENTATION

64. I reserve the right to modify and further supplement this report based on information that may subsequently become available in this matter, and to respond to issues yet to be raised in the litigation. I reserve the right to change or formulate new opinions if there is a material change in the law concerning patent infringement between now and trial.

XIV. DEMONSTRATIVE EXHIBITS

65. If called to testify at trial, I may prepare demonstrative exhibits, such as charts and graphs, to further explain my opinions.

Dated: 5/24/2022


Gregor Anderson

EXHIBIT B

EXHIBIT B

ADDITIONAL MATERIALS CONSIDERED BY GREGOR ANDERSON

- Materials Listed in Exhibit B to Anderson Opening Report
- '156 Patent Prosecution History
- April 29, 2022 Opening Expert Reports of David Lewis to Cipla and Aurobindo
- U.S. Patent No. 6,446,627 ("Bowman")